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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,470	07/21/2003	Debbi Drane	017227-0190	4517
22428 7590 06/06/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER LI, BAO Q	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 06/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/622,470	<b>Applicant(s)</b> DRANE ET AL.	
	<b>Examiner</b> Bao Qun Li	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 44-99 is/are pending in the application.
- 4a) Of the above claim(s) 56-62, 77-83 and 86-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 44-55, 63-76, 84 and 85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>March 27, 2007</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1648

## **DETAILED ACTION**

### **RCE**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/27/2007 has been entered. The REC follows:

### ***Response to Amendment***

This is a response to the amendment filed on 03/27/07. Claim 1 has been amended. Claims 2-43 have been canceled. Claims 1 and 44-99 are pending. Claims 56-62, 77-83, 86-99 were withdrawn from consideration. Claims 1, 44-55, 63-76 and 84-85 are considered before the examiner.

### ***Claim Rejections - 35 USC § 102 (b)***

1. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Applicant's arguments with respect to claims 1, 46, 47, 48, 49-55, 64, 67-76, 85 under 102 (b) s being anticipated by Garcon et al. WO 98/15287A1 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

3. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
4. Applicant's arguments with respect to claims 1, 44-55, 63-76, 84-85 under 103(a) as being unpatentable over Garcon et al. WO 98/15287A1 and Coppoer et al. (Immunity, 1999, April, Vol. 10, pp. 439-449) and John et al. (Hepatology 1999, Vol. 30, No. 4, pp. 1037-1044) have been considered but are moot in view of the new ground(s) of rejection.

New Ground rejection:

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 44-55, 63-76, 84-85 are rejected under 35 U.S.C. 112, **first paragraph**, as **containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.** In the instant case, claims 1 and 64 have been amended with a negative limitation that cites the immunogenic complex does not include alum. Applicants point out that the support for this limitation can be found in line 19 of page 26 of the current application. However, to the contrary of applicants' assertion, the specification on page 26 lines 17-20 of current application and page 31, 4<sup>th</sup> paragraph of the provisional application SN. 60/166,652 cite that "the vaccine composition may further include adjuvants to enhance the composition. Suitable adjuvant include, but not limited to alum ... ."

7. MPEP 2173.05 cites: Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Therefore, claims are rejected with new matter for this negative limitation.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

Art Unit: 1648

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1, 44, 46-55, 64-76, and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Simmonds et al. (A) (WO 94/25602A1) or under 35 U.S.C. 102(e) as being anticipated by Simmonds et al. (B) (US Patent No. 6,881,821B2) or (C) (US 7,198,892B2) in light of the teaching by Sjolander et al. (**Advanced Drug Delivery Reviews** Volume 34, Issues 2-3, 1 December 1998, Pages 321-338).

10. Simmonds et al. in patents (A to C) all teach to preparing HCV immunogenic composition by attaching the immunogenic peptide(s) derived from non-structural protein NS4, NS5 and core to a particular immunogenic carrier of liposomes or ISCOM (See page 24 of A, column 10 in B and column 11 in C). Because ISCOM inherently comprises the active ingredients of saponin and cholestertol. The structures inherently has a net negative charge as a result of glucuronic acid in the saponin structure and are highly stable in light of the teaching by Sjolander et al. They teach that ISCOMs has open cage-like complexes typically with a diameter of about 40 nm which are built up by cholesterol, lipid, immunogen and saponins from the bark of *Quillaia saponaria* Molina (soap bark tree). Sjolander et al. also concludes that ISCOM is a particulate adjuvant/antigen delivery system for developing a large number of human experimental vaccines (See abstract and Fig. Pages 325-328, and Fig. 2). None of references by Simmonds et al. or Sjolander et al. teach to use alum for conjugating the HCV antigen prior to contacting the HCV antigen to ISCOM complex.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 44-55, 63-76 and 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simmonds et al. (A) (WO 94/25602A1) or (B) or (C) as cited above in view of the teaching by Cerny et al. (J Clin Invest. 1995 Feb;95(2):521-30).

13. The claimed invention is directed to make an immunogenic composition comprising an immunogenic antigen derived from HCV antigen selected from at least one of the following antigen consisting of core, NS3, NS4, and NS5, which contains T cell epitope carried by immunostimulatory complex (ISCOM) made from saponin complex comprising saponin, cholesterol and method of using such composition induce a cytotoxic T cell response.

14. Simmonds et al. in patents (A to C) all teach to preparing HCV immunogenic composition by attaching the immunogenic peptide(s) derived from non-structural protein NS4, NS5 and core to a particular immunogenic carrier of liposomes or ISCOM (See page 24 of A, column 10 in B and column 11 in C). Because ISCOM inherently comprises the active ingredients of saponin and cholesterol. It also inherently has a net negative charge. Simmonds et al. do not teach that which HCV antigen peptide contains T cell epitope.

15. However, the T cell epitopes of HCV core, NS3, NS4 and NS5 had been identified and well described in the prior art prior to the current application was filed. Such as Cerny et al. teach many CTL epitopes with precise sequence structures (See table I to VI and Fig. 1-6 and entire document).

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filed to be motivated by the recited references and to combine the method taught by Simmonds et al. in (A) or (B) or (C) and Cerny et al. to select the right CTLK epitopes taught

Art Unit: 1648

by Cerny et al. and packaging the peptide antigen with ISCOM for producing an enhanced immune response with expected results.

17. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.


### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Bao Qun Li

May 29, 2007

BAOQUN LI, MD  
PATENT EXAMINER